

REMARKS

Claims 2-18 and 21-23 and 25-33 are pending. Claims 19-20 and 34-41 are withdrawn. By this amendment, claims 21-33 are canceled, claims 2, 3, 5, 7, and 10-18 are amended, and new claims 42-56 are added. Following entry of this amendment, claims 2-18, 42-56 will be under examination. Support for the amended claims is found in the originally filed claims and the specification, as further discussed below. No new matter is added by this amendment.

The rejection of claims 2-8, 10-18, 21-23, and 25-33 under 35 U.S.C. Section 103 is re-levied. Claim 9 is objected to but would be allowable if re-written as an independent claim. The Examiner did not state that the outstanding rejections of claims 5, 11, 16, 26, and 31 as indefinite under 35 U.S.C. § 112, second paragraph, but did not re-levy this rejection. Thus, this rejection does not apply to the claims currently under examination before entry of this amendment. Applicant notes that claims 2 and 10-18 were allowed in Paper No. 19, but presently stand rejected under 35 USC Section 103.

Interview and Information Disclosure Statement and

Applicant thanks the Examiner and his supervisor, Examiner Reynolds, for the courtesy of the helpful personal interview held August 18, 2003 with Applicant's representative and Applicant, Dr. Ralph Snodgrass. This response reflects the results of that interview. Applicant further thanks the Examiner for the brief telephonic interview held October 14, 2003, during which the amendments to claim 2 and new claim 42 were discussed. Applicant appreciates the Examiner's helpful suggestions in this regard.

Applicant notes that a Supplemental Information Disclosure Statement was submitted on August 29, 2000. Applicant would appreciate it if the Examiner could review the references and initial and return the 1449 submitted therewith.

Applicant notes with appreciation that the Office has accepted the formal drawings that were submitted with the last response.

As discussed during the interviews, claim 2 is amended to recite "a library of expression profiles correlated with a known toxic property of a chemical composition". New claims 42-47 also recite this language. Applicant believes that this amendment clarifies that the library comprises expression profiles which are relevant to toxicity, as suggested by the Examiner. Support for the amendment is found in the specification at, e.g., page 37, line 3-6; page 3, lines 15-16; page 26, lines 12-14, 20-23, 32-33; page 31, lines 15-17; Tables 1 and 2.

Further, as suggested by the Examiner, and discussed during the interviews, claim 2 (as well as claims 3, 5, and 7) has been amended to replace "expression of sets of genes or proteins" with "genomic expression." New claims 42-46 also recite this language. Support for the amendment is found in the specification at, e.g., page 8, lines 20-21.

Claim 2 (as well as claims 11-13 and 16-18) has also been amended to delete the phrase "having predetermined toxicities" (which Applicant submits is implicit in the new language quoted above), and to replace "molecular profile" with "expression profile" (see, e.g., specification at page 37, line 6; page 7, lines 14-21 and 27-30). The new claims also recite this language.

Claims 10, 14, and 15 have been amended to improve the grammar and consistency of the claims. The amendments are implicit in the claims as originally filed.

Claims 21-33 are cancelled. New claims 41-43 are similar to cancelled claims 21-23, but have been rewritten to delete step (a) of each claim (which referenced the method of now-cancelled claim 1); recite former step (b) as the first limitation (i.e., "comparing an expression profile of the test chemical composition with an expression profile of a chemical composition"); and recite that the expression profile of the test chemical composition is created by a method comprising the steps of "a) contacting a mammalian embryoid body with the test chemical composition; and b) detecting and recording alterations in genomic expression in the mammalian embryoid body in response to the

test chemical composition compared to genomic expression in a mammalian embryoid body not contacted with the test chemical composition, to create a pattern of alterations in genomic expression in the mammalian embryoid body in response to the test chemical composition." Support for these amendments is implicit in the claims as previously pending, and is further found in the specification, inter alia, at page 7, lines 26-30; page 9, lines 16-21; page 7, lines 14-21 and 27-30; *see also* claims 21-23, 2, and 1 as originally filed.

New claims 45 and 46 recite a method for assessing toxicity of a test chemical and a method for prioritizing drug development of a test chemical, respectively. Support for these claims is found in the specification, e.g., at page 2, lines 25-26; page 8, lines 20-21, page 9, line 26-29; page 27, line 12-15; page 11, line 12-14; page 8, line 22-25; page 27, line 18-21; *see also* claims 21-23, 2, and 1 as originally filed. New dependent claims 47-56 recite limitations that correspond to the limitations in previously pending claims 24-33. Support for these claims is found in originally filed claims 24-33.

With respect to all amendments and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

Rejection under 35 U.S.C. § 103(a)

The Office has rejected claims 2-8, 10-18, 21-23, and 25-33 under 35 U.S.C. Section 103 as allegedly obvious over Spielmann et al., 1997 (In Vitro Toxicology, Vol. 10, No. 1, p. 119-127) in view of Craig et al., 1996 (Biomarkers, Vol. 1, No. 2, p. 123-135 and Wobus et al., 1999 (US Patent 6,007,993). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference(s) must teach or suggest all the claim limitations. Second, there must be some

suggestion or motivation to modify the reference or to combine reference teachings. Third, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Applicant respectfully submits that a *prima facie* case of obviousness has not been made because the cited references do not teach or suggest all of the limitations of the rejected claims.

As a preliminary matter, as discussed during the interview, claim 2 has been amended to recite "detecting and recording alterations in genomic expression in the mammalian embryoid body in response to the chemical composition compared to genomic expression in a mammalian embryoid body not contacted with the chemical composition" (instead of "detecting and recording alterations in expression of sets of genes and protein"). New claims 42-27 also recite "genomic expression".

By contrast, Spielmann does not teach "detecting and recording alterations in genomic expression in the mammalian embryoid body in response to the chemical composition", as required by claims 2 and 42-27. As noted by the Examiner in the Office Action, Spielmann teaches detection of the percentage of embryoid bodies (EBs) that contain beating myocyte cells following addition of a test chemical to the EBs.

Neither Wobus nor Craig rectify the deficiencies of Spielmann. As discussed during the interview, Craig teaches detection of the expression of 32 known developmentally-regulated genes in the topminnow embryo in response to teratogen chemicals. Craig does not teach detecting and recording alterations in genomic expression, as required by the present claims. Applicant notes that the methods of the present invention works with the expression of both known and unknown genes, and do not require preselection of known developmentally-regulated genes, as taught by Craig.

Similarly, Wobus teaches detection of detection of reporter gene expression driven by a known developmentally-regulated promoter. Thus, Wobus does not teach detecting and recording alterations in genomic expression, as required by the present claims. Further, Wobus requires preselection of known developmentally-regulated genes. By contrast, the methods of the present

invention works with the expression of both known and unknown genes, and do not require preselection of known developmentally-regulated genes, as required by Wobus.

Thus, Applicant respectfully submits that the cited references do not teach or suggest all of the limitations of the present claims. Withdrawal of this rejection is respectfully requested.


CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the fee transmittal is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or fees due in connection with this document to **Deposit Account No. 03-1952** referencing docket no. 441472000100

Dated: October 14, 2003

Respectfully submitted,

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